

IN THE SPECIFICATION

Please amend the specification as follows. The paragraph numbers and text referenced match the paragraph numbers of the electronic copy of the published application available through PAIR.

Please amend paragraph 7 as follows:

[0007] The use of event codes to establish subcategories of blood glucose test results has an additional disadvantage or drawback. In particular, although alphanumeric display devices are typically used in currently available microprocessor-based blood glucose monitoring systems, the display units are limited to a single line of information having on the order of six characters. Moreover, since the systems include no provision for the user to enter alphanumeric information, any event codes that are used must be indicated on the display in a generic manner, e.g., displayed as ~~"EVENT"EVENT~~etc. "EVENT" etc. This limitation makes the system more difficult to use because the diabetic must either memorize his or her assignment of event codes or maintain a list that defines the event codes. The limited amount of data that can be displayed at any one time presents additional drawbacks and disadvantages. First, instructions and diagnostics that are displayed to the user when calibrating the system and using the system to obtain a blood glucose reading must be displayed a line at a time and in many cases, the information must be displayed in a cryptic manner.

Please amend paragraph 22 as follows:

[0022] The invention can be embodied in forms other than those described above. For example, although small handheld

~~microprocessorunits~~ microprocessor units such as a handheld video game system or handheld ~~microprocessorunits~~ microprocessor units of the type often referred to as "~~palmcomputers~~ palm computers provide many advantages, there are situations in which other compact ~~microprocessorunits~~ microprocesor units can advantageously be used. ~~Among the~~ The various types of units that can be employed ~~are~~ include using compact video game systems of the type that employ a program cartridge, but uses a television set or video monitor instead of a display unit that is integrated into the previously described handheld ~~microprocessorunits~~ microprocessor units.

Please amend paragraph 23 as follows:

[0023] Those skilled in the art also will recognize that the above-described microprocessor-implemented functions and operations can be apportioned between one or more microprocessors in a manner that differs from the above-described arrangement. For example, in some situations, the programmable ~~microprocessorunit~~ microprocessor unit and the program cartridge used in practicing the invention may provide memory and signal processing capability that is sufficient for practicing the invention. In such situations, the microprocessor of the microprocessor-based data management unit of the ~~aboveembodiments~~ above embodiments in effect is moved into the video game system, ~~palmcomputer~~ palm computer or programmable microprocessor device. In such an arrangement, the data management unit can be realized as a relatively simple interface unit that includes little or no signal processing capability. Depending upon the situation at hand, the interface unit may or may not include a telephone modem and/or an ~~RSconnection~~ RS connection (or other data port) for interconnecting the healthcare system with a computer or other equipment. In other situations, the functions and operations associated with processing of the monitored ~~health-care~~ healthcare data may be performed by a microprocessor that is added to or

already present in the monitoring device that is used to monitor blood glucose or other condition.

Please amend paragraph 24 as follows:

[0024] Because the invention can be embodied to establish systems having different levels of complexity, the invention satisfies a wide range of self-care health monitoring applications. The arrangements that include a modem (or other signal transmission facility) and sufficient signal processing capability can be employed in situations in which reports are electronically transmitted to a healthcare professional either in hard copy (facsimile) form or in a signal format that can be received by and stored in the healthcare professional's computer. On the other hand, less complex (and, hence, less costly) embodiments of the invention are available for use in which transfer of system information need not be made by means of telephonic data transfer or other remote transmission methods. In these less complex embodiments, transfer of data to a healthcare professional can still be accomplished. Specifically, if the program cartridge includes a battery and suitable program instructions, monitored healthcare data can be stored in the program cartridge during use of the system as a healthcare monitor. The data cartridge can then be provided to the healthcare professional and inserted in a programmable ~~microprocessorunit~~ microprocessor unit that is the same as or similar to that which was used in the healthcare monitoring system. The healthcare professional can then review the data, and record it for later use, and/or can use the data in performing various analyses. If desired, the ~~microprocessorunit~~ microprocessor unit used by the healthcare professional can be programmed and arranged to allow information to be stored in the cartridge for return to and retrieval by the user of the healthcare monitoring system. The stored information can include messages

(e.g., instructions for changes in medication dosage) and/or program instructions for reconfiguring the program included in the cartridge so as to effect changes in the treatment regimen, the analyses or reports to be generated by the healthcare monitoring system, or less important aspects such as graphical presentation presented during the operation of the health care system.

Please amend paragraph 31 as follows:

[0031] FIG. 1 depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIG. 1 a data management unit 10 is electrically interconnected with a handheld microprocessor-based unit 12 via a cable 14. In the depicted arrangement, data management unit 10 also is electrically interconnected with a blood glucose monitor 16 of the type capable of sensing blood glucose level and producing an electrical signal representative thereof. Although FIG. 1 illustrates blood glucose monitor 16 as being connected to data management unit 10 by a cable 18 it may be preferable to construct blood ~~glucose~~ glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Regardless of the manner in which blood glucose monitor 16 is interconnected with data management unit 10 both that interconnection and cable 14 are configured for serial data communication between the interconnected devices.

Please amend paragraph 32 as follows:

[0032] Also shown in FIG. 1 are two additional monitoring devices 20 and 22 which are electrically connected for serial data communication with data management unit 10 via cables 24 and 26 respectively. Monitoring units 20 and 22 of FIG. 1 represent devices other than blood glucose monitor 16 that can be used to configure the invention for self-care health monitoring

applications other than (or in addition to) diabetes care. For example, as is indicated in FIG. 1 the monitoring device 20 can be a peak-flow meter that provides a digital signal representative of the airflow that results when a person suffering from asthma or another chronic respiratory affliction expels a breath of air through the meter. As is indicated by monitor 22 of FIG. 1 various other devices can be provided for monitoring conditions such as blood pressure, pulse, and body temperature to thereby realize systems for self-care monitoring and control of conditions such as hypertension, certain heart conditions and various other afflictions and physical conditions. Upon understanding the hereinafter discussed aspects and features of the invention it will be recognized that the invention is easily implemented for these and other types of healthcare monitoring. In particular, monitors used in the practice of the invention can be arranged in a variety of ways as long as the data to be recorded or otherwise employed by handheld microprocessor unit 12 and/or data management unit 10 is provided in serial format in synchronization with clock signals provided by data management unit 10. As is the case with blood glucose monitor 16 the additional monitors can be configured as plug-in units that are directly received by data management unit 10 or can be connected to data management unit 10 with cables (as shown in FIG. 1). As is shown in FIG. 1, handheld microprocessor unit 12 includes a display screen 28 and a plurality of switches or keys (30, 32, 34, 36, and 38 in FIG. 1) which are mounted on a housing 40. Located in the interior of housing 40 but not shown in FIG. 1 are a microprocessor, memory circuits, and circuitry that interfaces switches 30, 32, 34, 36 and 38 with the microprocessor. Stored in the memory of program handheld microprocessor unit 12 is a set of program instructions that establishes a data protocol that allows handheld microprocessor unit 12 to perform digital data signal processing and generate desired data or graphics for display

on display unit 28 when a program cartridge 42 is inserted in a slot or other receptacle in housing 40. That is, program cartridge 42 of FIG. 1 includes read-only memory units (or other memory means such as battery-powered random access memory) which store program instructions and data that adapt handheld microprocessor for operation in a blood glucose monitoring system. More specifically, when the instructions and data of program cartridge 42 are combined with program instructions and data included in the internal memory circuits of handheld microprocessor unit 12, handheld microprocessor unit 12 is programmed for processing and displaying blood glucose information in the manner described below and additional monitors to provide health monitoring for asthma and various other previously mentioned chronic conditions. In each case, the plurality of switches or keys (30, 32, 34, 36, and 38 in FIG. 1) are selectively operated to provide signals that result in pictorial and/or alphanumeric information being displayed by display unit 28. Various devices are known that meet the above-set forth description of handheld microprocessor unit 12. For example, compact devices are available in which the plurality of keys allows alphanumeric entry and internal memory is provided for storing information such as names, addresses, phone numbers, and an appointment calendar. Small program cartridge or cards can be inserted in these devices to program the device for various purposes such as the playing of games, spreadsheet application, and foreign language translation sufficient for use in travel. More recently, less compact products that have more extensive computational capability and are generally called "palm top computers" have been introduced into the marketplace. These devices also can include provision for programming the device by means of an insertable program card or cartridge.

Please amend paragraph 34 as follows:

[0034] Another advantage of realizing handheld microprocessor unit 12 in the form of a compact video game system is the relatively simple, yet versatile arrangement of switches that is provided by such a device. For example, as is indicated in FIG. 1 a compact video game system includes a control pad 30 that allows an object displayed on display unit 28 to be moved in a selected direction (i.e., up-down or left-right). As also is indicated in FIG. 1 compact video game systems typically provide two pair of distinctly-shaped push button switches. In the arrangement shown in FIG. 1 a pair of spaced-apart circular push button switches (36 and 38) and a pair of ~~elongate~~ elongated switches (32 and 34) are provided. The functions performed by the two pairs of switches is dependent upon the program instructions contained in each program cartridge 42. Yet another advantage of utilizing a compact video game system for handheld microprocessor-based unit of FIG. 1 is the widespread popularity and low cost of such units. In this regard, manufacture and sale of a data management unit 10 blood ~~glucose~~ glucose monitor 16 and program cartridge 42 that operate in conjunction with a compact microprocessor-based video allows the self-care health monitoring system of FIG. 1 to be manufactured and sold at a lower cost than could be realized in an arrangement in which handheld unit is designed and manufactured solely for use in the system of FIG. 1. An even further advantage of using a compact video game system for handheld microprocessor is that such video game systems include means for easily establishing the electrical interconnection provided by cable in FIG. 1. In particular, such compact video game systems include a connector mounted to the game unit housing (40 in FIG. 1) and a cable that can be connected between the connectors of two video game units to allow interactive operation of the two interconnected units (i.e., to allow contemporaneous game play by two players or competition between

players as they individually play identical but separate games). In the preferred embodiments of the invention, the "two-player" cable supplied with the compact video game unit being used as handheld microprocessor unit 12 is used as ~~cable to~~ cable to establish serial data communication between the handheld microprocessor unit 12 (compact video game system) and data management unit 10. In these preferred embodiments, the program instructions stored on the memory of data management unit 10 and program cartridge 42 respectively program data management unit 10 and the compact video game system (i.e., handheld microprocessor unit 12) for interactive operation in which switches 30, 32, 34, 36 and 38 are used to control the operation of data management unit 10 (e.g., to select a particular operational mode such as performance of a blood glucose test or the display of statistical test data and, in addition, to control operation such as selection of an option during operation of the system in a particular operational mode). In each operational mode, data management unit 10 processes data in accordance with program instructions stored in the memory circuits of data management unit 10. Depending upon the operational mode selected by the user, data is supplied to data management unit 10 by blood ~~glucose~~ glucose monitor 16 by additional monitors (20 and 22 in FIG. 1) or any interconnected computers or data processing facility (such as the hereinafter described user's computer 48 and clearinghouse 54 of FIG. 1). During such operation, mode switches and are selectively activated so that signals are selectively coupled to the video game system (handheld microprocessor unit 12 and processed in accordance with program instructions stored in program cartridge 42. The signal processing performed by handheld microprocessor unit 12 results in the display of alphanumeric, symbolic, or graphic information on the video game display screen 28 (i.e., display unit 28 in FIG. 1 which allow the user to control

system operation and obtain desired test results and other information.

Please amend paragraph 37 as follows:

[0037] As is indicated in FIG. 1 data management unit 10 of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit 10 and a remote computing facility identified in FIG. ~~as 1~~ as clearinghouse 54 via a conventional telephone line 64 (indicated by reference numeral 50 in FIG. 1 and a modem 52 that interconnects clearinghouse 54 and telephone line 50. As shall be described in more detail, clearinghouse computing facility 54 facilitates communication between a user of the system shown in FIG. 1 and his or her healthcare professional and can provide additional services such as updating system software. As is indicated by facsimile machine 55 of FIG. 1, a primary function of clearinghouse 54 is providing the healthcare professional with standardized reports 56, which indicate both the current condition and condition trends of the system user. Although a single facsimile machine 55 is shown in FIG. 1 it will be recognized that numerous healthcare professionals (and hence facsimile machine 55 can be connected in signal communication with a clearinghouse 54. Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIG. 1 provide a self-care blood glucose monitoring system in which program cartridge 42 (a) handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) handheld microprocessor unit 12 for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) handheld

microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled to data management unit 10 from a clearinghouse 54. The manner in which the arrangement of FIG. 1 implements the above-mentioned functions and others can be better understood with reference to FIGS. 2 and 3. Referring first to FIG. 1 clearinghouse 54 receives data from a plurality of self-care microprocessor-based healthcare systems of the type shown in FIG. 1 with the individual self-care health monitoring systems being indicated in FIG. 2 by reference numeral. Preferably, the data supplied to clearinghouse 54 by each individual self-care health monitoring system consists of "raw data," i.e., test results and related data that was stored in memory circuits of data management unit 10 without further processing by data management unit 10. For example, with respect to the arrangement shown in FIG. 1 blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse 54 and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

Please amend paragraph 38 as follows:

[0038] As shall be recognized upon understanding the manner in which it operates, clearinghouse 54 can be considered to be a central server for the various system users (58 in FIG. 2) and each healthcare professional 60. In that regard, clearinghouse 54

includes conventionally arranged and interconnected digital processing equipment (represented in FIG. 2 by digital signal processor 57) which receives digitally encoded information from a user 58 or healthcare professional 60; processes the information as required; stores the information (processed or unprocessed) in memory if necessary; and, transmits the information to an intended recipient (i.e., user 58 or healthcare professional 60. In FIG. 2 rectangular outline 60 represents one of numerous remotely located healthcare professionals who can utilize clearinghouse 54 and the arrangement described relative to FIG. 1 in monitoring and controlling patient healthcare programs. Shown within outline 60 is a computer 62 (e.g., personal computer), which is coupled to clearinghouse 54 by means of a modem (not shown in FIG. 2 and a telephone line 64. Also shown in FIG. 2 is the previously mentioned 55 which is coupled to clearinghouse 54 by means of a second telephone line 68. Using the interface unit of computer 62 (e.g., a keyboard or pointing device such as a mouse), the healthcare professional can establish data communication between computer 62 and clearinghouse 54 via telephone line. Once data communication is established between computer and clearinghouse 54, patient information can be obtained from clearinghouse 54 in a manner similar to the manner in which subscribers to various database services access and obtain information. In particular, the healthcare professional can transmit an authorization code to clearinghouse 54 that identifies the healthcare professional as an authorized user of the clearinghouse 54 and, in addition, can transmit a signal representing the patient for which healthcare information is being sought. As is the case with conventional database services and other arrangements, the identifying data is keyed into computer by means of a conventional keyboard (not shown in ~~FIGURE~~ FIG. 2) in response to prompts that are generated at clearinghouse 54 for display by the display unit 28 of computer

(not shown in FIG. 2). Depending upon the hardware and software arrangement of clearinghouse 54 and selections made by the healthcare professional via computer patient information can be provided to the healthcare professional in different ways. For example, computer 62 can be operated to access data in the form that it is stored in the memory circuits of clearinghouse 54 (i.e., raw data that has not been processed or altered by the computational or data processing arrangements of clearinghouse 54. Such data can be processed, analyzed, printed and/or displayed by computer using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse 54 with the results of the analyses being transmitted to the remotely located healthcare professional. For example, clearinghouse 54 can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIG. 1. With respect to such processing and any other analysis and processing provided by clearinghouse 54 results expressed in alphanumeric format can be sent to computer via telephone line 50 and the modem associated with computer with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference.

Please amend paragraph 39 as follows:

[0039] The arrangement of FIG. 2 also allows the healthcare professional to send messages and/or instructions to each patient via computer telephone line and clearinghouse 54. In particular, clearinghouse 54 can be programmed to generate a menu that is displayed by computer and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse 54 for subsequent transmission to a user of the system described relative to FIG. 1. This same menu (or related submenus) can be used by the healthcare professional to select one

or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse 54 is provided to the healthcare provider via computer and/or facsimile machine 55. In the currently contemplated arrangements, operation of the arrangement of FIG. 2 to provide the user of the invention with messages or instructions such as changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a patient, i.e., transmitted to clearinghouse 54 by a data management unit 10 of FIG. 1. The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer. Once the data is entered and transmitted to clearinghouse 54 it is stored for subsequent transmission to the user for whom the information or instruction is intended.

Please amend paragraph 40 as follows:

[0040] With respect to transmitting stored messages or instructions to a user of the invention, at least two techniques are available. The first technique is based upon the manner in which operational modes are selected in the practice of the invention. Specifically, in the currently preferred embodiments of the invention, program instructions that are stored in data management unit 10 and program cartridge 42 cause the system of FIG. 1 to generate menu screens which are displayed by display unit 28 of handheld microprocessor unit 12. The menu screens allow the system user to select the basic mode in which the system of FIG. 1 is to operate and, in addition, allow the user to select operational subcategories within the selected mode of operation. Various techniques are known to those skilled in the art for displaying and selecting menu items. For example, in the practice of this invention, one or more main menus can be generated and displayed which allow the system user to

select operational modes that may include: (a) a monitor mode (e.g., monitoring of blood glucose level); (b) a display mode (e.g., displaying previously obtained blood glucose test results or other relevant information); (c) an input mode (e.g., a mode for entering data such as providing information that relates to the healthcare regimen, medication dosage, food intake, etc.); and (d) a communications mode (for establishing a communication link between data management unit 10 and personal computer 48 of FIG. 1 or between data management unit 10 and a remote computing facility such as clearinghouse 54 of FIG. 2). In embodiments of the invention that employ a compact video game system for handheld microprocessor unit 12 the selection of menu screens and the selection of menu screen items preferably is accomplished in substantially the same manner as menu screens and menu items are selected during the playing of a video game. For example, the program instructions stored in data management unit 10 and program cartridge 42 of the arrangement of FIG. 1 can be established so that a predetermined one of the compact video game switches (e.g., switch 32 in FIG. 1 allows the system user to select a desired main menu in the event that multiple main menus are employed. When the desired main menu is displayed, operation by the user of control pad 30 allows a cursor or other indicator that is displayed on the menu to be positioned adjacent to or over the menu item to be selected. Activation of a switch (e.g., switch of the depicted handheld microprocessor unit ~~12~~ 12) causes the handheld microprocessor unit 12 and/or data management unit 10 to initiate the selected operational mode or, if selection of operational submodes is required, causes handheld microprocessor unit 12 to display a submenu.

Please amend paragraph 43 as follows:

[0043] Practicing the invention in an environment in which the healthcare professional uses a personal computer in some or all of the above-discussed ways can be very advantageous. On the other hand, the invention also provides healthcare professionals timely information about system users without the need for a computer (62 in FIG. 2) or any equipment other than a conventional facsimile machine (55 in FIGS. 1 and 2). Specifically, information provided to clearinghouse 54 by a system user can be sent to a healthcare professional 60 via telephone line 68 and facsimile machine 55 with the information being formatted as a standardized graphic or textual report (56 in FIG. 4 1). Formatting a standardized report 56 (i.e., analyzing and processing data supplied by blood ~~glucose~~ glucose monitor 16 or other system monitor or sensor) can be effected either by data management unit 10 or within the clearinghouse 54 facility. Moreover, various standardized reports can be provided (e.g., the textual and graphic displays discussed below relating to FIGS. 6-10). Preferably, the signal processing arrangement included in clearinghouse 54 allows each healthcare professional 60 to select which of several standardized reports will be routinely transmitted to the healthcare professionals' facsimile 55, and, to do so on a patient-by-patient (user-by-user) basis.

Please amend paragraph 44 as follows:

[0044] FIG. 3 illustrates the manner in which data management unit 10 is arranged and interconnected with other system components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGS. 4-10. As is symbolically indicated in FIG. 3 handheld microprocessor unit 12 and blood ~~glucose~~ glucose monitor 16 are connected to a dual universal asynchronous receiver transmitter 70 (e.g., by cables 14

and 18 of FIG. 1 respectively). As also is indicated in FIG. 3 when a system user connects a personal computer 48 (or other programmable digital signal processor) to data port 44, signal communication is established between personal computer 48 and a second dual universal asynchronous receiver transmitter 72 of data management unit 10. Additionally, dual universal asynchronous receiver transmitter 72 is coupled to modem 46 so that data communication can be established between data management unit 10 and a remote clearinghouse 54 of FIGS. 1 and 2. Currently preferred embodiments of data management unit 10 include a plurality of signal sensors 74, with an individual signal sensor being associated with each device that is (or may be) interconnected with data management unit 10. As previously discussed and as is indicated in FIG. 3, these devices include handheld microprocessor unit 12, blood ~~glucose~~ glucose monitor 16, personal computer 48, remote computing facility 54 and, in addition, peak-flow meter 20 or other additional monitoring devices. Each signal sensor 74 that is included in data management unit 10 is electrically connected for receiving a signal that will be present when the device with which that particular signal sensor is associated is connected to data management unit 10 and, in addition, is energized (e.g., turned on). For example, in previously mentioned embodiments of the invention in which data port 44 is an RS-232 connection, the signal sensor 74 that is associated with personal computer 48 can be connected to an RS-232 terminal that is supplied power when a personal computer is connected to data port 44 and the personal computer is turned on. In a similar manner, the signal sensor 74 that is associated with clearinghouse 54 can be connected to modem 46 so that the signal sensor 74 receives an electrical signal when modem 46 is interconnected to a remote computing facility (e.g., clearinghouse 54 of FIG. 2) via a telephone line 50. In the arrangement of FIG. 3, each signal sensor 74 is a low power switch

circuit (e.g., a metal-oxide semiconductor field-effect transistor circuit), which automatically energizes data management unit 10 whenever any one (or more) of the devices associated with signal sensors 74 is connected to data management unit 10 and is energized. Thus, as is indicated in FIG. 3 by signal path 76 each signal sensor 74 is interconnected with power supply 78 which supplies operating current to the circuitry of data management unit 10 and typically consists of one or more small batteries (e.g., three AAA alkaline cells).

Please amend paragraph 45 as follows:

[0045] The microprocessor and other conventional circuitry that enables data management unit 10 to process system signals in accordance with stored program instructions is indicated in FIG. 3 by central processing unit (CPU) 80. As is indicated in FIG. 3 ~~by~~ by interconnection 82 between CPU 80 and battery 78, CPU 80 receives operating current from power supply 78 with power being provided only when one or more of the signal sensors 74 are activated in the previously described manner. A clock/calendar circuit 84 is connected to CPU 80 (via signal path 86 in FIG. 3 ~~3~~) to allow time and date tagging of blood glucose tests and other information. Although not specifically shown in FIG. 3 operating power is supplied to clock/calendar 84 at all times.

Please amend paragraph 46 as follows:

[0046] In operation, CPU 80 receives and sends signals via a data bus (indicated by signal path 88 in FIG. 3 3) which interconnects CPU 80 with dual universal asynchronous receiver transmitters 70 and 72. The data bus 88 also interconnects CPU 80 with memory circuits which, in the depicted embodiment, include a system read-only memory (ROM) 90 a program random access memory (RAM) 92 and an electronically erasable read-only memory (EEROM) 94. System ROM 90

stores program instructions and any data required in order to program data management unit 10 so that data management unit 10 and a handheld microprocessor unit 12 that is programmed with a suitable program cartridge 42 provide the previously discussed system operation and, in addition, system operation of the type described relative to FIGS. 4-10. During operation of the system, program RAM 92 provides memory space that allows CPU 80 to carry out various operations that are required for sequencing and controlling the operation of the system of FIG. 1. In addition, RAM 92 can provide memory space that allows external programs (e.g., programs provided by clearinghouse 54 to be stored and executed. EEROM 94 allows blood glucose test results and other data information to be stored and preserved until the information is no longer needed (i.e., until purposely ~~erased~~ erased) by operating the system to provide an appropriate erase signal to EEROM 94. FIGS. 4-10 illustrate typical screen displays that are generated by the arrangement of the invention described relative to FIGS. 1-3. Reference will first be made to FIGS. 4 and 5 which exemplify screen displays that are associated with operation of the invention in the blood glucose monitoring mode. Specifically, in the currently preferred embodiments of the invention, blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to: (a) a test or calibration sequence in which tests are performed to confirm that the system is operating properly; and, (b) the blood glucose test sequence in which blood glucose meter 16 senses the user's blood glucose level. Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a "code strip," that is inserted in the monitor and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration procedure is used in the

practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a "monitor" menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIG. 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIG. 4 display screens that indicate a potential malfunction of the system include a prominent message such as the "Attention" notation included in the screen display of FIG. 4. As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor 16. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

Please amend paragraph 47 as follows:

[0047] In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIG. 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step

monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor-based blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line or less at a time. For example, as is shown in FIG. 5 the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIG. 3). The arrangement shown and described relative to FIGS. 1-3 also is advantageous in that data relating to food intake, concurrent medication dosage and other conditions easily can be entered into the system and stored with the time and date tagged blood glucose test result for later review and analysis by the user and/or his or her healthcare professional. Specifically, a menu generated by the system at the beginning or end of the blood glucose monitoring sequence can include items such as "hypoglycemic" and "hyperglycemic," which can be selected using the switches of handheld microprocessor unit 12 (e.g., operation of control pad 30 and switch 36 in FIG. 1) to indicate the user was experiencing hypoglycemic or hyperglycemic symptoms at the time of monitoring blood glucose level. Food intake can be quantitatively entered in terms of "Bread Exchange" units or other suitable terms by, for example, selecting a food intake menu item and using a

submenu display and the switches of handheld microprocessor 12 to select and enter the appropriate information. A similar menu item--submenu selection process also can be used to enter medication data such as the type of insulin used at the time of the glucose monitoring sequence and the dosage.

Please amend paragraph 49 as follows:

[0049] The screen display shown in FIG. 8 is representative of statistical data that can be determined by the system of FIG. 1 (using conventional computation techniques) and displayed in alphanumeric format. As previously mentioned, such statistical data and information in various other textual and graphic formats can be provided to a healthcare professional (60 in FIG. 2) in the form of a standardized report 56 (FIG. 1) that is sent by clearinghouse 54 to facsimile machine 55. In the exemplary screen display of FIG. 8 statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests is provided. In the exemplary display of FIG. 8, the system (data management unit 10 or clearinghouse 54 also calculates and displays (or prints) the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in FIG. 8); and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.

Please amend paragraph 53 as follows:

[0053] It will also be recognized by those skilled in the art that the invention can be embodied in forms other than the embodiments described relative to FIGS. 1-10. For example, the invention can employ compact video game systems that are configured differently than the previously discussed handheld video game systems and palm computers. More specifically, as is shown in FIG. 11, a self-health monitoring system arranged in accordance with the invention can employ a compact video game system of the type that includes one or more controllers 100 that are interconnected to a game console 102 via cable 104. As is indicated in FIG. 11 game console 102 is connected to a video monitor or television 106 by means of a cable 108. Although differing in physical configuration, controller 100, game console 102, and the television or video monitor 106 collectively function in the same manner as the handheld microprocessor 12 of FIG. 1. In that regard, a program cartridge 42 is inserted into a receptacle contained in game console 102 with program cartridge 42 including stored program instructions for controlling microprocessor circuitry that is located inside game console 102. Controller 100 includes a control pad 30 or other device functionally equivalent to control pad 30 of FIG. 1 and switches that functionally correspond to switches 32-38 of FIG. 1. Regardless of whether the invention is embodied with a handheld microprocessor unit 12 (FIG. 1) or an arrangement such as the compact video game system (FIG. 11) in some cases it is both possible and advantageous to apportion the signal processing functions and operations differently than was described relative to FIGS. 1-10. For example, in some situations, the microprocessor-based unit that is programmed by a card or cartridge (e.g., handheld unit 12 of FIG. 1 or compact video game console of FIG. 11) includes memory and signal processing capability that allows the microprocessor to perform all or most of the functions and

operations attributed to data management unit 10 of the embodiments discussed relative to FIGS. 1-10. That is, the digitally encoded signal supplied by blood glucose monitor 16 (or one of the other monitors 20 and 22 of FIG. 1) can be directly coupled to the microprocessor included in game console 102 of FIG. 11 or handheld microprocessor 12 of FIG. 1. In such an arrangement, the data management unit 10 is a relatively simple signal interface (e.g., interface unit of FIG. 11) the primary purpose of which is carrying signals between the blood glucose monitor 16 (or other monitor) and the microprocessor of game console 102 (FIG. 11) or handheld unit 12 (FIG. 1). In some situations, the interface unit may consist primarily or entirely of a conventional cable arrangement such as a cable for interconnection between RS-232 data ports or other conventional connection arrangements. On the other hand, as is shown in FIG. 11 signal interface 110 can either internally include or be connected to a modem 52, which receives and transmits signals via a telephone line 50 in the manner described relative to FIGS. 1 and 2.

Please amend paragraph 54 as follows:

[0054] It also should be noted that all or a portion of the functions and operations attributed to data management unit 10 of FIG. 1 can be performed by microprocessor circuitry located in blood ~~glucose~~ glucose monitor 16 (or other monitor that is used with the system). For example, a number of commercially available blood glucose monitors include a clock/calendar circuit of the type described relative to FIG. 3 and, in addition, include microprocessor circuitry for generating visual display signals and signals representative of both current and past values of monitored blood glucose level. Conventional programming and design techniques can be employed to adapt such commercially available units for the performance of the various functions and operations attributed in

the above discussion of FIGS. 1-11 to data management unit 10 and/or the microprocessors of handheld unit 12 and compact video console 102. In arrangements in which the blood glucose monitor 16 (or other system monitor) includes a microprocessor that is programmed to provide signal processing in the above-described manner, the invention can use a signal interface unit 110 of the above-described type. That is, depending upon the amount of signal processing effected by the monitoring unit (e.g., blood ~~glucose~~ glucose monitor 16) and the amount of signal processing performed by the microprocessor of video game console 102 (or handheld unit 12) the signal interface required ranges from a conventional cable (e.g., interconnection of RS-232 ports) to an arrangement in which signal interface 110 is arranged for signal communication with an internal or external modem (e.g., modem 52 of FIG. 11) or an arrangement in which signal interface 110 provides only a portion of the signal processing described relative to FIGS. 1-10. The invention also is capable of transmitting information to a remote location (e.g., clearinghouse 54 and/or a remotely located healthcare professional) by means other than conventional telephone lines. For example, a modem (52 in FIGS. ~~at~~ 1 and 11) that is configured for use with a cellular telephone system can be employed to transmit the signals provided by the healthcare monitoring system to a remote location via modulated RF transmission. Moreover, the invention can be employed with various digital networks such as recently developed interactive voice, video and data systems such as television systems in which a television and user interface apparatus is interactively coupled to a remote location via coaxial or fiberoptic cable and other transmission media (indicated in FIG. 11) by cable 112 which is connected to television or video monitor. In such an arrangement, compact video game controller and the microprocessor of video game console 102 can be programmed to provide the user interface functions required

for transmission and reception of signals via the interactive system. Alternatively, the signals provided by video game console 102 (or handheld ~~unit~~ if unit of FIG. 1) can be supplied to the user interface of the interactive system (not shown in FIG. 11) in a format that is compatible with the interactive system and allows the system user interface to be used to control signal transmission between the healthcare system and a remote facility such as clearinghouse 54 of FIGS. 1 and 2.